

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

In re:
Levaquin Products
Liability Litigation

Multi-District Litigation
08-md-1943

This document refers to:
ALL CASES

DECLARATION OF KEITH ALTMAN

I am an attorney licensed to practice in the State of California, and am currently the managing director for the complex litigation department as well as the director of adverse event analysis for the law firm of Finkelstein & Partners located in Newburgh, New York. Previous to this, I was the vice president of The Fibonacci Group located in Philadelphia, PA. A true copy of my curriculum vitae (C.V.) is attached to this report as Exhibit "1".

My primary business is providing litigation consulting services relating to discovery and analysis of electronic and paper information in complex litigation. Since 1989, I have been extensively involved in the collection and analysis of electronic information. I have developed several data analysis tools and worked on hundreds of data conversion projects.

I have been involved in several mass tort litigations related to drugs and other medical devices. These litigations include breast implant, FenPhen, Rezulin, Propulsid, Baycol, PPA, Accutane, Meridia, Hormone Replacement Therapy, Neurontin, Lariam,

Ortho-Evra, Depakote, Lexapro, Avandia, and Vioxx. In these litigations, I am involved in the development of document discovery protocols and assist counsel throughout the discovery process. As a routine part of my business activities, I collect and analyze adverse event data from the Food and Drug Administration ("FDA") and pharmaceutical companies. The FDA has made its data available to the general public in several sections, and I have accumulated a complete set of data from the FDA for all of the adverse events in the FDA databases for all drugs since 1969. I have normalized the data so that the data from each of the sets could be combined into a single database. I continue to add events to this data on a quarterly basis and my database is current through the second quarter of 2009. I provide these services on an ad hoc basis to the general public, and am routinely asked to compile adverse event information on numerous drugs and provide this data in a variety of formats and reports. In general, these analyses are objective in nature, and represent accumulation and summary of large amounts of data. While I employ substantial technical expertise, the work that I do is exactly reproducible by anyone with similar skills and is not reasonably subject to dispute.

I also have performed professional services for pharmaceutical companies. To date, I have performed the safety analyses for several new drug applications (NDA's) which have been approved. I wrote the post marketing section of the integrated summary of safety for one of them. These projects required that all of the available FDA data be accumulated based on several different variables. As part of the review of the NDA, the FDA examines my work. Several of these NDA's have received their approval and

marketing has commenced. I have been retained to provide similar services for other drugs in the near future.

In my professional capacity I have provided assistance to the FDA with respect to its handling of data. In mid 2003, I detected a flaw in the data provided by the FDA as part of its adverse event reporting extracts made available to the general public. This flaw would likely have led to serious errors in working with the data. I communicated my discovery with Paul Reinstein of the FDA, who is the individual responsible for the extract of the FDA AERS data. As a result of my discovery, the FDA has abandoned the practice that affected the data, and communicated this decision publicly to all users of the AERS data worldwide.

Over the past 12 years, I have developed several tools for the presentation of data from adverse event databases. I use generally accepted methods for the calculation of the percentages of adverse event reports for a particular event compared to all events received at that time. Once the percentages are calculated, then can be compared between one drug and another and a ratio can be computed if desired. This type of analysis is called proportional reporting rate analysis ("PRR") and has been used world wide for more than 10 years. In its 2005 Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment, the FDA recognized PRR as one of the standard methods of signal detection and data mining.

I am a member of the International Society for Pharmacoepidemiology ("ISPE"). ISPE is the preeminent worldwide organization for drug safety issues and those who study adverse pharmaceutical adverse events. Over that past three years, I have

presented my methods, used in this case, to the society. In 2007, I submitted three abstract proposals for posters to be presented at the annual meeting of ISPE, all of which were accepted. One of the abstracts was selected for an oral presentation on methods. In 2009, two additional abstracts were submitted for posters and were accepted. Recently in 2010 another poster was presented and I was also granted another oral presentation, specifically concerning the methods used to create the charts in this case. Only a small portion of the submitted abstracts are selected for oral presentations and both require peer review by members of the society.

In this case, I collected data from two sources. The first was the J&J internal adverse event database, SCEPTRE. The second was the publicly available data from the FDA. With respect to the FDA data, I calculated percentages of reports for adverse event terms over time for Levaquin, Cipro, and Floxin. For each drug at quarterly intervals, I calculated the percentage of reports for each adverse event term as compared to all reports. Because I did not use any subjective judgment and relied upon the coding as provided in the publicly available FDA data, these results are not subject to any reasonable dispute and could be easily verified by obtaining the publicly available FDA data. Once I calculated these percentages, I plotted them for each drug over time. The resulting charts allow a reader to see the evolution of the reporting rates for the various drugs over time.

I declare under penalties of perjury that the foregoing statement is true and correct to the best of my knowledge.

/s Keith Altman
Keith Altman

Dated: October, 13 2010 Massapequa Park, NY